

REMARKS

It is respectfully submitted that the present application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-11 are pending in the present application. Claim 1 has been amended to recite that the volumes of the wells are within the range of 0.1-20 microliter.

In the outstanding Official Action, claims 1-2 and 9-11 were rejected under 35 USC 102(e) as allegedly being anticipated by PALL et al. This rejection is respectfully traversed.

Applicants believe that PALL et al. fail to anticipate the claimed invention. As the Examiner is aware, a claim is anticipated only if each and every recitation as set forth in the claim is found either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. vs. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Circ. 1987).

Applicants believe that PALL et al. fail to teach a test device wherein the wells have the claimed volume. PALL et al. disclose a device for separating plasma from blood. The device has a fibrous structure. Blood is applied at one region and the components move along the fiber due to the absorbing property of the fiber. During this process, a plasma front

advances ahead of the red cell boundary. By doing so, plasma is separated.

However, as noted above, claim 1 has been amended to recite that the volumes of the wells are within the range of 0.1-20 microliter. As a result, applicants submit that PALL et al. fail to anticipate the claimed invention. Applicants also believe that PALL et al. fail to render obvious the claimed test device.

The device according to PALL et al. is not a test device according to the present invention. This is demonstrated by column 11, line 21. Indeed, column 11, line 28 refers to Figure 3. Figure 3 does not show a test device comprising a well. Figure 3 shows two strips that are attached to each other.

Rather, PALL et al. state that "A test specimen was then cut from the laminate with its length parallel to the fiber orientation to obtain an integral self bonded strip 0.437 cm wide by 2.6 cm long shown in perspective as item 1 in Fig. 3."

Moreover, column 11, lines 30-35 describe that blood was placed in contact with one end of the strip and plasma was separated and collected. Even if this strip were considered to be a test device comprising a well, it would still not be a test device according to the present invention because the volume of the strip is more than 20 microliters.

This is shown in column 11, lines 32-35, which states that the average volume of plasma collected was 5.7 μ l with an

average efficiency of 27.7%. Column 9, lines 62-62 shows how an efficiency is calculated: the volume of plasma collected is divided by the volume of blood supplied and multiplied by 100. Hence, a volume of collected plasma of 5.7 μ l with an efficiency of 27.7% means that 20.6 microliter of blood was supplied ($5.7/20.6 \times 100 = 27.7$). Thus, a strip according to PALL et al. has a volume of at least 20.6 microliter.

Moreover, a further volume has to be available in order to allow the blood components to move to a second region of the strip, during which process plasma is separated from the blood. A strip according to PALL et al., therefore, has a significantly larger volume than 20 microliter.

Indeed, when PALL et al. do refer to a plate with wells, PALL et al. state that a standard plate is used. With this in mind, applicants note that the specification explains in detail as to why the claimed invention is distinct from standard plates (see page 1, lines 11-16).

Thus, PALL et al. fails to anticipate the claimed invention.

Claims 3-8 were rejected under 35 USC 103(a) as allegedly being unpatentable over PALL et al. This rejection is respectfully traversed.

Applicants respectfully submit that PALL et al. also fail to render obvious claims 3-8. As previously noted, applicants do not believe that the densities of the wells would

be a parameter that would be readily optimized by one of ordinary skill in the art. Indeed, as the Examiner is aware, a particular parameter or variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the parameter or variable might be characterized as routine or obvious. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Indeed, PALL et al. are completely silent as to the claimed depth, diameter ratio of the wells and the density of the plate. As a result, it cannot be said that PALL et al. characterize these parameters as routine or obvious.

At this time, the Examiner is also respectfully reminded that a critical step in analyzing obviousness pursuant to 35 U.S.C. §103(a) is casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, only guided by the publications and then-accepted wisdom in the field. Close adherence to this methodology is important in cases where the invention itself may prompt an Examiner to "fall victim to the insidious effect of a hindsight syndrome, wherein that which only the invention taught is used against its teacher." Indeed, to establish a prima facie case of obviousness, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ 2d

1313, 1362 (Fed. Circ. 2000). The fact that the prior art could be so modified would not have made the modification itself obvious unless the cited publications themselves suggested the desirability of the modification. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Circ. 1984).


Thus, applicants believe that the publications fail to disclose or suggest the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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